COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13-V-2005
C(2005)1521

NOT FOR PUBLICATION

COMMISSION DECISION

of 13-V-2005

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

ONLY THE GERMAN TEXT IS AUTHENTIC

COMMISSION DECISION

of 13-V-2005

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application submitted by Aventis Pharma Deutschland GmbH on 17 December 2004 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 16 March 2005,

Whereas:

(1) An examination of the major variation type II to the terms of the marketing authorisation for the medicinal product "Apidra - Insulin glulisine", which is entered in the Community Register of Medicinal Products under No(s) EU/1/04/285/001-020 and the placing on the market of which was authorised by

[1] OJ L 214, 24.8.1993, p. 1. Regulation as last amended by [Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19)].
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by [Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).]

Decision C(2004)3653 of 27 September 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to accept the application in respect of a major variation to the terms of the marketing authorisation and to amend Decision C(2004)3653 accordingly.

(3) During the same period, Aventis Pharma Deutschland GmbH submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet. The competent authority did not oppose the proposed change within the 90-day time-limit.

(4) The marketing authorisation should be updated, and Decision C(2004)3653 amended accordingly.

(5) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)3653 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3653 is amended as follows:

1) The list of notifications for changes to an aspect of the labelling or the package leaflet, accepted between 15 March 2005 and 16 March 2005, is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/000557/N/0003	IIIA (EU/1/04/285/001-020)

2) Annex I is replaced by the text set out in the Annex I to this Decision.

3) Annex III is replaced by the text set out in the Annex III to this Decision.

4) The following numbers are added to Article 1 and entered in the Community register of medicinal products:

EU/1/04/285/021	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass) for OptiClik-3 ml-1 cartridge

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by [Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34)].

EU/1/04/285/022	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass) for OptiClik-3 ml-3 cartridges
EU/1/04/285/023	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass) for OptiClik-3 ml-4 cartridges
EU/1/04/285/024	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass) for OptiClik-3 ml-5 cartridges
EU/1/04/285/025	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass) for OptiClik-3 ml-6 cartridges
EU/1/04/285/026	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass) for OptiClik-3 ml-8 cartridges
EU/1/04/285/027	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass) for OptiClik-3 ml-9 cartridges
EU/1/04/285/028	Apidra-100 U/ml-Solution for injection-Subcutaneous use-cartridge (glass) for OptiClik-3 ml-10 cartridges

Article 2

This Decision is addressed to Aventis Pharma Deutschland GmbH, Brueningstrasse 50, D-65926 Frankfurt am Main, Deutschland.

Done at Brussels, 13-V-2005

For the Commission
Günter VERHEUGEN
Member of the Commission